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REMARKS

Claims 26, 28 to 42 and 45 to 57 are pending. Claims 26 and 28 have been amended herein and claim 57 has been cancelled. Therefore, claims 26, 28 to 42 and 45 to 56 are presently under examination.

Regarding the claim amendments

Claims 26 and 28 have been amended to recite either 6 to 100 contiguous amino acids of SEQ ID NO:2 (claim 26) or 6 to 50 contiguous amino acids of SEQ ID NO:2 (claim 28). Support for these amendments can be found throughout the specification, for example, at page 17, lines 2-4, which discloses portions of SEQ ID NO:1 useful, for example, as primers for PCR analysis, and at page 6, line 29, to page 7, line 1, which discloses the I-2 nucleic acid sequence (SEQ ID NO:1) and predicted amino acid sequence (SEQ ID NO:2). Additional support for these amendments can be found at page 42, lines 3-15, which discloses recombinant nucleic acid molecules encoding peptide fragments of an I-2 polypeptide, and at page 51, lines 23-26, which discloses the I-2 specific primers SEQ ID NOS:3 and 4. Support for recitation that the isolated nucleic acid molecule encodes at least six or between 6 and 100 contiguous amino acids of SEQ ID NO:2 is provided throughout the specification, for example, at page 13, lines 1-15, which discloses amino acid sequences having between 6 and 100 residues of an I-2 polypeptide (SEQ ID NO:2), and at

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page 10, lines 16-19, which discloses fragments having "contiguous" amino acids of SEQ ID NO:2.

Thus, the amendments are supported by the specification and do not add new matter. Applicants therefore request that the Examiner enter the amendments.

Regarding the rejection of claims 26, 28 to 31, 42, 45, 46 and 57 under 35 U.S.C. § 102(e) over Rubenfield et al.

The rejection of claims 26, 28 to 31, 42, 45, 46 and 57 under 35 U.S.C. § 102(e) as allegedly anticipated by Rubenfield et al. (U.S. Patent No. 6,551,795) is respectfully traversed.

The Office Action asserts that Rubenfield et al. describe an isolated nucleic acid molecule containing a portion of SEQ ID NO:1 encoding 8 contiguous amino acids of SEQ ID NO:2. Specifically, the Office Action points to nucleic acid sequence SEQ ID NO:9721 and amino acid sequence SEQ ID NO:26292 set forth in the sequence listing of Rubenfield et al. as allegedly anticipating the claimed invention.

The rejected claims are directed to an isolated nucleic acid molecule containing a portion of SEQ ID NO:1 that encodes a specified number of contiguous amino acids of SEQ ID NO:2 (claims 26, 28 to 31 and 57) or to an isolated nucleic acid molecule containing a nucleic acid sequence encoding the

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specified number of contiguous amino acids of SEQ ID NO:2 (claims 42, 45 and 46).

Applicants respectfully submit that claims 26, 28 to 31, 42, 45, 46 and 57 are novel over Rubenfield et al. because the cited patent is not prior art with respect to the claimed invention. In this regard, while the earliest priority date of Rubenfield et al. is February 18, 1998, Applicants obtained the claimed I-2 nucleic acid sequence prior to this date. As evidence that the February 18, 1998, priority date of Rubenfield et al. was later than Applicants' date of invention, Applicants submit herewith a Declaration under 37 C.F.R. § 1.131 by inventors Jonathan Braun and Christopher Sutton, together with copies of relevant laboratory documents. In the Declaration, the dates of the laboratory documents have been redacted; however, the dates shown on the original sheets indicate that Applicants had obtained the claimed I-2 nucleic acid sequence prior to February 18, 1998.

In sum, because the claimed invention was made prior to the February 18, 1998, priority date of Rubenfield et al., this patent is not prior art with respect to the claimed invention. Accordingly, Applicants respectfully request that the rejection of claims 29 to 31, 42, 45, 46 and 57 under 35 U.S.C. §102(e) be removed.

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Regarding the rejection of claims 32 to 41 and 47 to 56 under 35 U.S.C. § 103(a) over Rubenfield et al.

The rejection of claims 32 to 41 and 47 to 56 under 35 U.S.C. § 103(a) as allegedly anticipated by Rubenfield et al. (U.S. Patent No. 6,551,795) is respectfully traversed.

The Office Action alleges that Rubenfield et al. describes an amino acid sequence having 25 consecutive amino acids of SEQ ID NO:2, and argues that all possible degenerate sequence variations resulting in an expression product having the sequence GEAMAVLVYEWRSLSAEQA, are obvious in view of the cited patent.

Applicants respectfully submit that claims 32 to 41 and 47 to 56 are unobvious over the cited reference. In particular, as described above with respect to the rejection of claims 26, 28 to 31, 42, 45, 46 and 57 under 35 U.S.C. § 102(e), the cited patent is not prior art with respect to the claimed invention. Thus, Applicants request removal of this rejection under 35 U.S.C. § 103(a) over Rubenfield et al.

Regarding the rejection of claims 26 and 28 under 35 U.S.C. § 103(a) over Meyer et al.

The rejection of claims 26 and 28 under 35 U.S.C. § 103(a) as allegedly obvious over Meyer, Accession number Q59306, is respectfully traversed.

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As stated in the previous Office Action, Meyer appears to report the amino acid sequence HFKSK, which is contained in a 190 amino acid sequence encoded within an EcoRI-Sau3A *Clostridium pasteurianum* fragment. Although no nucleic acid sequence is reported in the cited reference, the Office Action alleges that the claimed isolated nucleic acid molecules are rendered obvious by the HFKSK sequence.

Applicants respectfully maintain that the isolated nucleic acid molecules of claims 26 and 28 are unobvious over the cited reference. Claims 26 and 28 are directed to an isolated nucleic acid molecule that includes a portion of SEQ ID NO:1 encoding at least 5 contiguous amino acids of SEQ ID NO:2, or encoding 5 to 50 contiguous amino acids of SEQ ID NO:2, respectively.

The question of whether a nucleotide sequence is rendered obvious by a prior art disclosure of the corresponding amino acid sequence has been examined by the federal court in *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995). In its review of the relevant case law, the Deuel Court observed that obviousness of a new chemical entity had always depended on whether the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention. In Deuel, the prior art did not disclose any relevant cDNA molecules, let alone close relatives of the specific, structurally defined cDNA molecules of the claimed invention. In particular, the Deuel Court indicated that

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while the general idea of the claimed molecules, their function, and their chemical structure may have been obvious from Bohlen's teachings, and the knowledge that some gene existed may have been clear, the precise cDNA molecules of claims 5 and 7 would not have been obvious over the Bohlen reference because Bohlen teaches proteins, not the claimed or closely related cDNA molecules. (Id. 1215.)

Applying the Deuel reasoning to the claimed invention and cited art, Meyer et al. suggests that a polypeptide existed which contained the sequence HFKSK but does not teach any portion of SEQ ID NO:1. In particular, the precise cDNA molecules of claims 26 and 28, which comprise portions of SEQ ID NO:1, were not taught in Meyer et al., nor are they obvious from this reference. In this regard, the Deuel Court clearly stated its rationale that

one could not have conceived the subject matter of claims 5 and 7 based on the cited prior art because, until the claimed molecules were actually isolated and purified it would have been unlikely for one of ordinary skill to contemplate what was ultimately obtained. What cannot be contemplated or conceived cannot be obvious. (Id. 1215.)

Analogously, one of ordinary skill in the art would not have conceived of the claimed sequences based on Meyer et al. and that which was known in the art regarding gene cloning and expression strategies. At most, the cited art would have motivated one of ordinary skill to search for the claimed sequences. According to Deuel, that is not enough to render the claimed sequences obvious:

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[The PTO theory] also ignores the fact that claims 5 and 7 are limited to specific compounds, and any motivation that existed was a general one, to try and obtain a gene that may have constituted many forms. A general motivation to search for some gene does not render obvious a specifically-defined gene that is subsequently obtained as a result of that search. More is needed and it is not found here. (Id. 1215.)

In the present case, the Examiner's assertion that "the degeneracy of the genetic code perfectly exemplifies the functional equivalency of all codons which encode the same single amino acid" also is in contrast to conclusions drawn in Deuel:

The genetic code relationship between proteins and nucleic acids does not overcome the deficiencies of the cited references. A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein. (Id. 1215.)

Therefore, Meyer et al. in reporting an amino acid sequence do not render obvious the claimed nucleic acid molecule, which contains a portion of the specific nucleotide sequence SEQ ID NO:1. Nevertheless, to further prosecution, claims 26 and 28 have been amended to recite between 6 and 100 contiguous amino acids of SEQ ID NO:2, and 6 to 50 contiguous amino acids of SEQ ID NO:2, respectively. Applicants submit that claims 26 and 28 as amended are non-obvious over Meyer et al. At best, the reference reports a polypeptide containing a 5 amino acid segment included in SEQ ID NO:2 but does not teach or suggest an isolated nucleic acid molecule containing a portion of SEQ ID NO:1 that encodes between 6 and 100 contiguous amino acids of SEQ ID NO:2.

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In view of the above remarks, Applicants respectfully request that the Examiner remove the rejection of claims 26 and 28 as allegedly obvious under 35 U.S.C. § 103(a) over Meyer et al.

CONCLUSION

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned agent or Cathryn Campbell.

Respectfully submitted,

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Date

Pamela M. Guy
Pamela M. Guy
Registration No.: 51,228
Telephone No. (858) 535-9001
Facsimile No. (858) 535-8949

McDERMOTT, WILL & EMERY
4370 La Jolla Village Drive
7th Floor
San Diego, California 92122